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| 09/358,788 | 07/22/1999 | MICHAEL J. HELLER | 0031/81494/JPW/GC | 1976 |
| 23432 | 7590 | 10/18/2011 | EXAMINER | |
| COOPER & DUNHAM, LLP | | | FORMAN, BETTY J | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/358,788 | Applicant(s) HELLER ET AL. | |
| | Examiner Betty Forman | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 49,57,58 and 79-82 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 49,57,58 and 79-82 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 26 August 2011 in which claims 49 and 57 were amended and claim 82 was added to re-state claim 49 as previously presented. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 27 May 2011 are maintained.

Applicant's arguments have been thoroughly reviewed and are discussed below. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 49, 57-58 and 79-82 are under prosecution.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

Art Unit: 1634

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 49, 57-58 and 79-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,017,696 in view of Cozzette (U.S. Patent No. 5,063,081) and Hollis et al (U.S. Patent No. 5,846,708, filed 23 April 1992).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for analyzing a nucleic acid sample by hybridization on electronically addressable microlocations wherein hybridization stringency is electronically controlled to remove non-specifically hybridized targets. The claim sets merely differ in the arrangement of limitations within the claim sets. For example, independent Claim 49 of the instant claim set defines electronic stringency control while dependent Claims 7, 15 and 45 of the '696 claim set

Art Unit: 1634

provides this limitation. The claim sets further differ in that the instant claims further define the microlocations as comprising permeation and attachment layers.

Cozzette teaches a method similar to the patent comprising immobilizing a binding partner (e.g. DNA) onto one of a plurality of electrodes, contacting with the complementary binding partner and detecting the interaction (Column 52, lines 4-20). Cozzette further teaches the method includes adding a probe complementary to a portion of the target that is not hybridized to the immobilized probe in a sandwich format and detecting formation of the sandwich (Column 52, lines 11-15). Cozzette also teaches that the permselective layer also acts as an adhesion promoter for the attachment layer thereby facilitating biomolecule immobilization (paragraph spanning columns 13-14).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the permselective and attachment layers of Cozzette to the patent electrodes. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Cozzette. The artisan would have been further motivated to do so for the expected benefits of providing a barrier against interfering ionic species while allowing transport of smaller detectable moieties of interest and facilitating biomolecule immobilization as desired in the art (Cozzette, paragraph spanning columns 13-14).

Additionally, the instant claims are further drawn to subjecting the microlocations to electric field prior to hybridization. However, concentrating sample molecules at microelectrode locations was well known in the art at the time the invention was made

Art Unit: 1634

as taught by Hollis who specifically teaches that application of an electric field enhances hybridization (paragraph spanning columns 13-14):

An electrical potential can draw charged target structures directly to probes near to or attached to the electrodes, increasing both the rate of hybridization and the total number of target/probe hybridizations that can be conveniently produced in a given experiment

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the patent method by applying an electric field to attract target molecules to the hybridization site to thereby increase the hybridization rate and number of hybridization events as taught by Hollis (paragraph spanning columns 13-14).

4. Claims 49, 57-58 and 79-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,048,690 in view of Cozzette (U.S. Patent No. 5,063,081) and Hollis et al (U.S. Patent No. 5,846,708, filed 23 April 1992).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for analyzing a nucleic acid sample by hybridization on electronically addressable microlocations wherein hybridization stringency is electronically controlled to remove non-specifically hybridized targets. The claim sets merely differ in that the instant claims define the structure of the electronic stringency control device e.g. microlocations comprising permeation and attachment layers while the patent is silent regarding the structure.

However, Cozzette teaches the structure of the electronic device including a permselective layer also acts as an adhesion promoter for the attachment layer thereby facilitating biomolecule immobilization (paragraph spanning columns 13-14).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the permselective and attachment layers of Cozzette to the patent electrodes. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Cozzette. The artisan would have been further motivated to do so for the expected benefits of providing a barrier against interfering ionic species while allowing transport of smaller detectable moieties of interest and facilitating biomolecule immobilization as desired in the art (Cozzette, paragraph spanning columns 13-14).

Additionally, the instant claims are further drawn to subjecting the microlocations to electric field prior to hybridization. However, concentrating sample molecules at microelectrode locations was well known in the art at the time the invention was made as taught by Hollis who specifically teaches that application of an electric field enhances hybridization (paragraph spanning columns 13-14).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the patent method by applying an electric field to attract target molecules to the hybridization site to thereby increase the hybridization rate and number of hybridization events as taught by Hollis (paragraph spanning columns 13-14).

5. Claims 49, 57-58 and 79-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 5,849,486 in view of Cozzette (U.S. Patent No. 5,063,081) and Hollis et al (U.S. Patent No. 5,846,708, filed 23 April 1992).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for analyzing a nucleic acid sample by hybridization on electronically addressable microlocations wherein hybridization stringency is electronically controlled to remove non-specifically hybridized targets. The claim sets merely differ in that the instant claims define the structure of the electronic stringency control device e.g. microlocations comprising permeation and attachment layers while the patent is silent regarding the structure.

However, Cozzette teaches the structure of the electronic device including a permselective layer also acts as an adhesion promoter for the attachment layer thereby facilitating biomolecule immobilization (paragraph spanning columns 13-14).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the permselective and attachment layers of Cozzette to the patent electrodes. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Cozzette. The artisan would have been further motivated to do so for the expected benefits of providing a barrier against interfering ionic species while allowing transport of smaller detectable moieties of interest and facilitating biomolecule immobilization as desired in the art (Cozzette, paragraph spanning columns 13-14).

Additionally, the instant claims are further drawn to subjecting the microlocations to electric field prior to hybridization. However, concentrating sample molecules at microelectrode locations was well known in the art at the time the invention was made as taught by Hollis who specifically teaches that application of an electric field enhances hybridization (paragraph spanning columns 13-14).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the patent method by applying an electric field to attract target molecules to the hybridization site to thereby increase the hybridization rate and number of hybridization events as taught by Hollis (paragraph spanning columns 13-14).

6. Claims 49, 57-58 and 79-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,582,421 in view of Hollis et al (U.S. Patent No. 5846708, filed 23 April 1992).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for analyzing a nucleic acid sample by hybridization on electronically addressable microlocations comprising a permeation layer wherein hybridization stringency is electronically controlled to remove non-specifically hybridized targets.

The claim sets merely differ in the arrangement of limitations within the claim sets. For example, independent Claim 49 of the instant claim set defines electronic

Art Unit: 1634

stringency control while dependent Claim 8 of the patent provides this limitation. The claim sets further differ in that the patent defines additional steps of fluorescent labeling and detection. However, the open claim language "comprising" of the instant claims encompasses the additional elements of the patent claims.

Therefore the instant claims are generic to the patent claims and therefore an obvious embodiment.

It is noted that Claims 1 and 6 of the '421 patent are drawn to application of an electric field prior to hybridization.

Additionally, the instant claims are further drawn to subjecting the microlocations to electric field prior to hybridization. However, concentrating sample molecules at microelectrode locations was well known in the art at the time the invention was made as taught by Hollis who specifically teaches that application of an electric field enhances hybridization (paragraph spanning columns 13-14).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the patent method by applying an electric field to attract target molecules to the hybridization site to thereby increase the hybridization rate and number of hybridization events as taught by Hollis (paragraph spanning columns 13-14).

Response to Arguments

7. Applicant asserts that none of the patented methods are drawn to subjecting individual electrodes to an electric field prior to hybridization.

The argument has been considered but is not sufficient to overcome the new grounds for rejection based on the amendments.

As noted above, concentrating sample molecules at microelectrode locations was well known in the art at the time the invention was made as taught by Hollis who specifically teaches that application of an electric field enhances hybridization (paragraph spanning columns 13-14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the patent method by applying an electric field to attract target molecules to the hybridization site to thereby increase the hybridization rate and number of hybridization events as taught by Hollis (paragraph spanning columns 13-14).

Additionally, Claim 1 of the '421 patent is specifically drawn to:

electronically biasing the sample nucleic acid to a test site of the plurality of test sites on the microchip, and concentrating the sample nucleic acid at the test site;

Claim 6 of the '421 patent is further drawn to:

electronically biasing the another sample nucleic acid to an another test site of the plurality of test sites on the microchip, concentrating the another sample nucleic acid at the another test site

It is unclear to the examiner how these elements of Claims 1 and 6 differ from the newly claimed subjecting locations to an electric field prior to hybridization.

Additionally, should Applicant choose to traverse the rejection based on a different interpretation of the claims (patent and/or instant) the application of an electric field prior to hybridization was well-known in the art as taught by Hollis and as discussed above.

Conclusion

8. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Forman whose telephone number is (571)272-0741. The examiner can normally be reached on 6:00 TO 3:30.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Betty Forman
Primary Examiner
Art Unit 1634

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